

# **Exhibit K**

SHARI ALLEN O'QUINN - Direct

1 no objection.

02:07:48

2 THE COURT: All right. 5197 is admitted.

3 (Exhibit Number 5197 was admitted into evidence.)

4 MR. NORTH: You can take that down now.

5 BY MR. NORTH:

02:07:53

6 Q. What else did Bard do to address these reports of  
7 migration with the Recovery filter?

8 A. We did a very thorough investigation. We got our  
9 engineers. We had engaged physicians as medical experts to  
10 give us input over time. We also conducted surveys, we got  
11 physician panels together. We communicated frequently with the  
12 FDA to share this information with them as well.

02:08:13

13 Q. Now, during this time, did Bard decide to update its  
14 instructions for use?

15 A. Yes.

02:08:40

16 Q. Did it also decide to send any sort of communication to  
17 physicians about these incidents?

18 A. Yes, we did. We updated the IFU and shared that with the  
19 FDA and then sent a letter to physicians and shared that  
20 information with physicians in the letter.

02:08:57

21 MR. NORTH: If we could look at 5196, please.

22 Q. Who was Mary Edwards?

23 A. Mary Edwards was my supervisor at the time that I started  
24 at Bard.

25 Q. And so you reported to her?

02:09:26

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1 A. Yes, I did.

02:09:27

2 Q. And when she left the company, did you essentially take  
3 over her role in supervising regulatory affairs?

4 A. Yes, I did.

5 Q. Is this letter, 5196, a communication that Ms. Edwards  
6 made to the FDA regarding changes to the IFU?

02:09:40

7 A. Yes. This is the letter that Mary submitted to FDA  
8 providing them a copy of the changes to the IFU.

9 Q. Did it also provide them with copy with a proposed letter  
10 to clinicians about the modifications?

02:10:05

11 A. Yes, it did.

12 Q. And were you familiar generally with this letter going  
13 out?

14 A. Yes, I was.

15 MR. NORTH: Your Honor, at this time we would tender  
16 5196.

02:10:21

17 MR. JOHNSON: This one is subject to the agreement,  
18 Your Honor.

19 THE COURT: All right. This is admitted subject to  
20 further discussion of the parties.

02:10:28

21 (Exhibit Number 5196 was admitted into evidence.)

22 BY MR. NORTH:

23 Q. And did the company hear back from the FDA?

24 Well, let's look at 5195 if we could.

25 A. I would need to verify the correspondence. I believe so

02:10:45

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1 but I would want to verify.

02:10:48

2 BY MR. NORTH:

3 Q. Let's look at 5195. Does this appear to be comments or a  
4 response from the FDA to Ms. Edwards' letter in October of  
5 2004?

02:11:19

6 A. Yes, it is. That's the response from FDA and they said  
7 that they approved the language in the Dear Doctor letter with  
8 some additional comments.

9 MR. NORTH: Your Honor, at this time we would tender  
10 5195.

02:11:33

11 MR. O'CONNOR: I think this one is subject to the  
12 same agreement, Your Honor.

13 THE COURT: All right. Admitted subject to further  
14 discussion of the parties.

15 (Exhibit Number 5195 was admitted into evidence.)

02:11:41

16 MR. NORTH: Could we display this to the jury, Your  
17 Honor?

18 THE COURT: Yes.

19 BY MR. NORTH:

20 Q. If we could look down about the third sentence beginning  
21 "The language."

02:11:52

22 So did the FDA actually provide comments on the Dear  
23 Doctor letter that Bard intended to send out to physicians  
24 regarding the changes to the instructions for use?

25 A. Yes.

02:12:20

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SHARI ALLEN O'QUINN - Direct

1 Q. Did Bard comply with the FDA's directions and make those  
2 changes?

3 A. Yes.

4 Q. And did Bard send this letter out and also revise the IFU  
5 as it had discussed with the FDA?

6 A. Yes.

7 Q. Why did Bard want FDA's input on this letter?

8 A. We wanted to be very proactive with the FDA to make sure  
9 that we were being transparent with them about the rates. We  
10 wanted to make sure that they were comfortable with the  
11 language, that we had appropriately disclosed the risks to  
12 physicians and we wanted to make sure that they approved the  
13 content.

14 MR. NORTH: Let's look at 5001, please.

15 BY MR. NORTH:

16 Q. Did you identify 5001 for us?

17 A. Yes. This is the Dear Doctor letter that we sent to  
18 physicians.

19 Q. And was that sent in approximately December of 2004?

20 A. I don't see the date on the letter to confirm but I recall  
21 that it was about that time.

22 MR. NORTH: Your Honor, at this time we would tender  
23 5001.

24 MR. O'CONNOR: No objection, Your Honor.

25 THE COURT: Admitted.

United States District Court